

## **REMARKS/ARGUMENTS**

### **Introduction**

The Examiner has rejected claims 1-5, 9-13 and 15-18, which represent all the currently pending claims in the application. Based on the remarks below, reconsideration and withdrawal of the rejection are respectfully requested.

### **Rejections under 35 U.S.C. §112**

The Examiner has rejected claims 1-5, 9-13 and 15-18 under 35 U.S.C. §112, first paragraph as containing subject matter which was not described in the specification in such as way to enable one skilled in the art to which it pertains, or with which is it most easily connect, to make and/or use the invention. More specifically the Examiner states:

**It is unclear what the term “non-continuous”, as used in this application, means and therefore what structure it represents. Page 7, lines 21-22 of the specification states “Non-continuous, as used herein, refers to a tubular structure which is not substantially uninterrupted along its length”. It is unclear if “along its length” means that 1) the structure is interrupted as one follows the longitudinal axis of the tubular structure or 2) the structure is interrupted either as one follows the longitudinal axis of the tubular structure as one follows the circumference of the tubular structure and this interruption occurs along the length of the tubular structure (as shown at 4 in figure 1, for example). Further, it is unclear what the term “perimetrically non-continuous”, as used in this application means and therefore what structure it represents. It is unclear if this term means 1) that the structure is non-continuous as one follows the circumference of the tubular structure (as shown at 4 in figure 1, for example) or 2) that the structure is non-continuous as one follows either the circumference or the longitudinal axis of the tubular structure. An example of a structure which is non-continuous as one follows the longitudinal axis of the tubular structure is a series of members (indicated by reference numeral**

7 in figure 2) wherein each member is a 360 degree ring spaced longitudinally from the other rings. In this case, the "perimeter" is simply the entire surface of the tubular structure. Also, it appears that second body 7 (figure 2) and second body 10 (figure 3) extend only partially in the circumferential direction since they are termed "strips" in the specification. Yet, the second bodies (e.g. second bodies 7 and 10) are referred to as a tubular bodies throughout the specification. Thus, it is unclear from the disclosure if second bodies 7 and 10 are tubular bodies which extend completely 360 degrees circumferentially or not. In other words, it is unclear if each of the three rectangular blocks on the right side of figure 2 represents a tubular body which extends completely 360 degrees circumferentially or not. If it does, it is not seen how it can be considered a strip. If it does not, it is unclear where the other strips are which form a tube with the rectangular strip shown.

The rejection is respectfully traversed.

In summary, the Examiner has rejected claims 1-5, 9-13 and 15-18 because of the term "perimetrically non-continuous". The Examiner alleges that it is unclear whether "perimetrically non-non-continuous" means non-continuous along the tubular member circumference or non-continuous along the tubular member length.

By way of explanation, the specification on page 7, lines 19-22 indicates that the term "non-continuous" refers to a tubular structure which is not substantially uninterrupted along its length. The term "perimetrically" with regard to the tubular structure of the present invention refers to its circumference, or circumferentially. The term "perimetrically non-continuous" therefore refers to a tubular structure which is circumferentially not substantially uninterrupted along its length; i.e., as one proceeds longitudinally along the tubular body, the circumference is

at no place uninterrupted; or, in other words, at no place is there circumferential continuity. This can be seen with reference to second tubular body 4 in figure 1 which has no perimetrical (circumferential) continuity along its longitudinal expanse, i.e., the longitudinal strips are not connected in any way.

The Examiner has further objected to the use of the term "strip" as referred to in claims 16-18 of the present application. Applicants again point to the specification where strips are defined as piece of material having a longitudinal length greater than its width. See claims 16-18. This is supported by Figure 2 which shows ePTFE strips as defined arranged to form a tubular structure as shown at 5 and 7 in Figure 2. (Figure 5) shows ePTFE strips arranged circumferentially adjacent to form a tubular structure, and 7 shows ePTFE strips arranged longitudinally adjacent to form a tubular structure. The rejection is respectfully traversed.

Applicants believe that the claims as currently standing comply with the requirements of 35 U.S.C. §112, first paragraph. The rejection is therefore respectfully traversed. Reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph is respectfully requested.

**Rejections under 35 U.S.C. §103**

The Examiner has rejected claims 1-5, 9-13, 15 and 17 under 35 U.S.C. §103(a) as being unpatentable over European Patent No. 0893108 to Ray. More particularly, the Examiner states:

**Ray shows first substantially continuous PTFE tubular body 4, second perimetrically non-continuous tubular body (the longitudinally extending strips of the coupling member described in col. 9, lines 13-21) formed of polytetrafluoroethylene (as indicated in col. 16, lines 20-31) and support structure 6. The Ray specification fails to specifically state that axial and radial compliance is provided to the prosthesis. However, it would have been obvious that axial and radial compliance is provided to the prosthesis due to the gaps between the strips. As to claim 3, note col. 7, lines 24-26 which indicates that the coupling member may be located on the inner rather than the outer surface of the stent. As to claim 6, note col. 10, lines 42-46.**

The rejection is respectfully traversed. Ray discloses a kink-resistant stent graft with an ePTFE tube, a stent and coupling member. The coupling member in Ray is a ribbon which covers only a portion of at least one of the inner and outer surfaces of the stent and is utilized solely for securing the stent member and graft member to each other. The coupling member is circumferentially, or helically wound around the graft, see figures 1a, 1b, 1c, 2, 4, 5, 6, 7, and 8 of Ray.

A careful examination of the specification of Ray reveals the importance of the helical winding of the coupling member, an embodiment which is seen in each of the figures of Ray, see, e.g., col. 7, line 50-col. 9, line 12, where Ray continually refers to the advantages of using a helically wound coupling member.

The presently claimed invention of claim 1 on the other hand provides a first continuous ePTFE tubular body and a second tubular body formed of elongate polytetrafluoroethylene strips

arranged longitudinally in a non-overlapping relationship (perimetrically non-continuous). The Examiner points to one sentence as rendering claim 1 obvious, found in Ray on column 9, lines 17-20, "longitudinally extending strips of ribbon may be used and may be preferred when the coupling member is used in conjunction with other stent member configurations."

When this passage is taken in the broader context of the specification of Ray as a whole however, it is unclear what this sentence means. This especially true considering the requirement that the coupling member is helically wound. More particularly, the passage cited by the Examiner does not indicate in what direction the longitudinally extending strips are extending, but rather that the strips are in a longitudinally extending shape. Given the importance of the helical winding of the coupling member in Ray, it is postulated that the longitudinally extending strips may be extending in a circumferential direction in order to properly couple the stent to the graft in Ray.

Even if the Examiner's allegation (that the longitudinally extending strips of Ray are longitudinally arranged with regard to the tubular body) is accurate however, it is not specified in Ray whether the strips are non-overlapping, i.e., whether they are "perimetrically non-continuous along the tubular length." Further, this is not taught or suggested anywhere in Ray's disclosure, nor is it alleged by the Examiner that it is taught or suggested in Ray. The Examiner has therefore failed to make a *prima facie* case of obviousness. Reconsideration is respectfully requested.

The rejection based on 35 U.S.C. §103(a) is therefore respectively traversed. Withdrawal of the rejection and reconsideration are respectfully requested.

The Examiner has further rejected claims 16 and 18 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,398,803 to Layne et al. More specifically, the Examiner states:

**Layne et al show first perimetrically non-continuous polytetrafluoroethylene inner tubular body (one set of circumferentially arranged strips extending between openings 44 of the inner "lacey" graft described in col. 5, lines 29-42 and which extend longitudinally only a distance equal to the width of each opening as measured in the longitudinal direction of the tubular member), second perimetrically non-continuous outer tubular body (one set of circumferentially arranged strips extending between openings 44 of the outer "lacey" graft described in col. 5, lines 29-42), support structure 30, both the outer and inner tubular body being formed of strips 48. Since only a portion of the Layne et al. inner and outer "lacey" grafts are considered to meet the claimed terms "tubular inner body" and outer tubular body", these portions are each "non-continuous along the entire length of said tubular bodies" as claimed. In other words, the "lacey" graft shown in figure 2 may be considered as comprising a series of longitudinally extending interconnected bodies. The first body at the end of the graft is continuous around its circumference. The second body consists of a plurality of strips between the openings 44. The third body is continuous around its circumference and so on, with the bodies alternating between being circumferentially continuous and non-continuous.**

The rejection is respectfully traversed.

Applicant has addressed the 112 rejections and added clarifying remarks with regards to the term "perimetrically non-continuous". In view thereof, it is clear that Layne does not disclose a perimetrically non-continuous tubular body.

The Examiner however refers to "one set of circumferentially arranged strips extending between opening 44 . . . which extend longitudinally only a distance equal to the width of each opening." A close examination of Figure 2 in Layne however reveals that there is a first tubular body in ePTFE tubular sleeve 42. First tubular body 42 is not perimetrically non-continuous. The Examiner has taken apart the ePTFE tubular sleeve 42 into discrete parts despite the fact that this is not taught or suggested by Layne, and is in fact prohibited by the disclosure of Layne.

The Examiner is further postulating that an individual portion of the tubular body 42 showed in Layne is indeed a "first tubular structure". Still further, the Examiner alleges that "Layne's specification fails to specifically state that axial and radial compliance is provided to the prosthesis. However, it would have been obvious that axial and radial compliance is provided to the prosthesis due to the openings in the strips."

The Examiner has cut out a portion a monolithic tubular body shown at 42 in Figure 2 of Layne. After dismantling the contiguous sleeve, the Examiner has further alleged that it is obvious that such strips would give axial and radial compliance to the prosthesis of Layne et al. Layne, however, teaches a monolithic tubular structure shown as 42 in Figure 2. The monolithic

structure by its nature is not as compliant as the presently claimed non-continuous tubular body.

This is not a proper interpretation of a prior art reference. When considering a reference, the Examiner must take the reference as a whole for its entire teachings in order to determine whether it anticipates or renders an invention obvious. In the present case, the Examiner has dismantled a monolithic tubular structure and then further alleges that this dismantled structure now possesses the claimed elements of the present invention. It is in this dismantling, however, that provides the alleged compliance suggested by the Examiner.

This interpretation is prohibited with regard to Layne. Not only does the entire disclosure of Layne teach away from this interpretation, but the element itself as disclosed in the reference teaches away from the Examiner's interpretation. This is evident because the inner tubular structure 42 is **only** shown as monolithic tubular sleeve. The Examiner has taken the liberty of cutting a monolithic structure into parts and then alleging that this perimetrically non-continuous structure (provided by the deconstruction) provides the claimed axial and radial compliance of the present invention.

The Examiner has therefore failed to make a *prima facie* case of obviousness. The present invention provides first and second perimetrically non-continuous tubular bodies. This is not disclosed by Layne, and it is improper to cut and paste from the actual elements of the



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reference to arrive at the presently claimed invention. Further, it is certainly improper to allege that the claimed invention is obvious with regard to the selected elements of the reference, when the reference itself explicitly teaches away from the interpretation. Withdrawal and reconsideration are respectfully requested.

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**SUMMARY**

Applicant respectfully submits that claims 1-5, 9-13 and 15-18 are patentably distinct. This application is believed to be in condition for allowance. Favorable action thereon is therefore respectfully solicited.

Should the Examiner have any questions or comments concerning this application or this amendment, he is invited to contact the undersigned counsel.

Respectfully submitted,



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